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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,426	04/12/2004	Naweed Muhammad	524522001300	4034

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,426	MUHAMMAD ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,9-11,85-90,93,95,97-105,110,122-127,129-139 and 141-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,9-11,85-90,93,95,97-105,110,122-127,129-139 and 141-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/10, 7/23/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 1/04/10 and 7/23/10 were filed after the mailing date of the previous Office Action on 12/28/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 90 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 is dependent on claim 1 which recites that the formulation comprises 6-60% of a TRPV1 agonist, with no more than 5% optional components. If this is the case, the penetration enhancer cannot be more than 94% of the formulation , however claim 90 recites that the penetration enhancer is at least 95% of the formulation. This is not possible and confusing as to how much of the penetration enhancer is present in the formulation. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7, 9, 10, 11, 85, 86, 88, 89, 90, 93, 95, 97, 98, 99, 122-127, 129-139 and 141-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Robbins US 2001/0002406 hereafter '406 in view of Patel et al (USPN 4,863,970 hereafter '970) and Jun et al (USPN 6,299,902 hereafter '902).

The '406 application discloses a topical analgesic composition comprising capsaicin in a concentration above 5% to about 10% (abstract). The formulation is applied to the skin or mucosal surface and is applied to treat neuropathic pain [0008]. The formulation is applied along with a local anesthetic such as lidocaine [0009]. The capsaicin is present in the formulation in a preferred concentration of 7.5% [0015]. The formulation comprises a permeation enhancing composition to aid in the transmission of the capsaicin and analgesic through the skin [0013]. The formulation can be applied in a liquid form in a reservoir type transdermal patch device [0017]. The devices provide long term pain relief for as long as eight weeks after application Example 1. The transdermal device would house the topical formulation in the reservoir.

The reference differs from the instant claims in that it is silent to the penetration enhancers of the instant claims. Combinations of penetration enhancers is well known in the art

as seen in the ‘970 patent. The ‘970 patent discloses a topical formulation comprising a permeation enhancer formulation comprising a mixture of cell envelope permeation enhancers such as oleic acid, oleyl alcohol and propylene glycol (abstract). The topical liquid formulation can be used to apply a wide range of active agents including analgesics (col. 7, lin. 48-55, col. 8, lin. 49-57). The active agents are present in concentration from 0.1-10% (col. 8, lin. 12-22). The permeation enhancers are present in a concentration of up to 95% (Examples). It would have been obvious to combine the penetration enhancers of the '970 into the '406 application in order to provide enhanced drug transmission since both reference disclose topical analgesic formulation.

The 406 patent also differs from the instant claims by not disclosing a microemulsion as the topical capsaicin formulation. However, topical capsaicin microemulsions are know in the art as seen in the ‘902 patent. The ‘902 patent discloses a formulation comprising an analgesic such as lidocaine, a second compound such as capsaicin, a permeation enhancing composition comprising a combination of alcohols such as propylene alcohol (col. 5, lin. 50-col. 6, lin. 18). The formulation can take the form of a transdermal patch, plaster, lotion, cream or microemulsion (claims). It would have been obvious to formulate the combination into various topical dosage forms as seen in the '902 patent discloses similar compositions formulated in a variety of topical formulations from transdermal patches to microemulsions.

Regarding the duration of pain relief, it is the position of the Examiner that such limitations are inherent features of the formulation that are dependent on the compositional components of the formulation. Since a compound and its properties cannot be separated, a composition comprising the same components in the same concentration should inherently have

the same properties. As such, the combined prior art would have a capsaicin concentration of about 7.5%, with a permeation enhancing formulation making up the remaining composition. It is the position of the Examiner that the combination would be able to provide analgesia for at least eight weeks as seen in the '406 reference and longer based on the similarity to the instant claims. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

With these aspects in mind it would have obvious to combine the pain relieving formulation of the '406 application with the permeation enhancers formulation of the '970 patent in order to improve the permeation of the capsaicin without increasing skin irritation. It would have been obvious to formulate the combination it a variety of topical formulation including microemulsions as disclosed in the '902 patent since the reference discloses a similar formulation comprising capsaicin, lidocaine and alcohol based permeation enhancers. It would have been obvious since both references disclose topical analgesic formulation. One of ordinary skill in the art would have been motivated to combine the prior art with an expected result of a method of long-term pain relief.

Claims 85, 86, and 98-103 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Robbins US 2001/0002406 hereafter '406 in view of Patel et al (USPN 4,863,970 hereafter '970) and Hahn et al (USPN 5,756,107 hereafter '107).

As discussed above the '406/'970 reference combination provides a liquid formulation comprising capsaicin, an analgesic, and an alcohol based permeation enhancer. The reference

combination is however silent to the system comprising an applicator as recited in the claims. The use of an aerosol or swab application is known in the art for topical applications as seen in the '107 patent.

The '107 patent discloses a system comprising a topical analgesic formulation and an applicator (abstract, col. 15, lin. 20-32). The applicator system can comprise an aerosol can for applying the topical solution, or a swab or washcloth to apply the solution to the skin in order to reduce irritation (col. 15, lin. 25-30). The solution comprises a vehicle comprising alcohols and glycerols (col. 14, lin. 50-65). It would have been obvious to apply the formulation of the '406/970 patent by the methods and systems of the '107 patent since the reference discloses similar topical formulation that are gently applied to the skin.

With these things in mind it would have been obvious to apply the '406/'970 combination formulation into the application system of the '107 patent in order to provide topical analgesia safely while reducing skin irritation. One of or ordinary skill in the art would have been motivated to combine the prior art since each reference disclose similar topical formulations with alcohol based vehicles. It would have been obvious to combine the prior art with an expected result of a stable application system useful to treating pain.

Claims 85, 86, 98, 104, 105 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Robbins (US 2001/0002406 hereafter '406) in view of Patel et al (USPN 4,863,970 hereafter '970) and Beerse et al (USPN 5,968,539 hereafter '539).

As discussed above the '406/970 reference combination provides a liquid formulation comprising capsaicin, an analgesic, and an alcohol based permeation enhancer. The reference combination is however silent to the specific system comprising a removal step or kit providing this feature, however any known removal method such as rinsing the applied area would be appropriate. A specific step would have been obvious to one of ordinary skill in the art in order to restore the skin to its original state. It would have been obvious to also rinse the applied area with a removal formulation that would leave the skin in its original state or better. This can be seen in the '539 patent.

The '539 patent discloses a mild rinse/off formulation comprising antimicrobial agents that continues to protect the skin against further infection (abstract). The mildest formulation that is most gentle to the skin comprises surfactants such as polyethylene glycol in a concentration from about 20-70% (col. 15, lin. 35-45). The liquid products can be applied to the forearm after it has been wet using a water tap from a standard basin, the formulation is applied and rinsed away in the basin (col. 21, lin. 55-col. 22, lin. 14). It would have been obvious to rinse the skin with the formulation of the '539 patent since it is mild and would also protect the skin against further bacterial infection.

With these things in mind it would have been obvious to use the formulation in a kit or basin as described in the '539 in order to clean the skin and removes any of the harsh effects of the '406/'972 combination. It would have been obvious to combine the prior art as such with an expected result of a stable method of treating pain.

Response to Arguments

Applicant's arguments, see Remarks, filed 3/24/10, with respect to the rejection(s) of claim(s) 1,7,9-11,85,86,88-90,93,95,97-105,110,122-127,129-139,141-145 under 35 USC 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the above discussed prior art rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618